



Attorney's Docket No. 3477-116

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Pugh et al.

Confirmation No.: 6664

Filed:

Appl. No.: 09/029,872

Group Art Unit:

3738

June 29, 1998

Examiner:

P. Prebilic

For:

ARTIFICIAL STABILIZED COMPOSITION OF CALCIUM PHOSPHATE

PHASES PARTICULARLY ADAPTED FOR SUPPORTING BONE CELL

**ACTIVITY** 

July 9, 2004

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450



# SUPPLEMENTAL APPEAL BRIEF UNDER 37 CFR § 1.193(b)(2)

This Supplemental Appeal Brief is filed pursuant to 37 CFR §1.193(b)(2) and is filed concurrently with a Request for Reinstatement of Appeal, both of which are filed in response to the Final Office Action of January 12, 2004. This Brief supplements an Appeal Brief ("The First Appeal Brief") filed with the Notice of Appeal on October 28, 2003.

Many of the arguments presented in The First Appeal Brief are applicable to the nowpending rejections and, therefore, many sections from the First Appeal Brief are incorporated into this Brief by reference, as indicated below. A copy of the First Appeal Brief is attached hereto to facilitate review by the Examiner and the Board.

#### Real Party in Interest. 1.

The real party in interest in this appeal is Millenium Biologix, Inc., the assignee of the above-referenced patent application.

#### Related Appeals and Interferences. 2.

There are no related appeals and/or interferences involving this application or its subject matter.



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## 3. Status of Claims.

The present appeal involves Claims 1, 2, 6, 10, 12, 13, 22, 23, 25-29, 32-35, 37 and 38. Claim 28 has been indicated as allowable if rewritten in independent form. Claims 3-5, 7-9, 11, 14-21, 24, 30, 31, 36, and 39-46 have been canceled. The claims at issue, namely, Claims 1, 2, 6, 10, 12, 13, 22, 23, 25-27, 29, 32-35, 37 and 38, are set forth in the appendix of the First Appeal Brief, attached hereto.

# 4. Status of Amendments.

An Official Action was mailed March 3, 2003, finally rejecting pending Claims 1, 2, 6, 10, 12, 13, 22, 23, 25-29, 32-35, 37 and 38.

Applicants filed an Amendment After Final concurrently with the First Appeal Brief to correct an apparent typographical error in the dependency of Claims 6 and 10. In particular, Claims 6 and 10 are amended to depend from process Claim 13, and not composition Claim 1. That Amendment After Final was entered when the Examiner reopened prosecution after the Appeal was filed.

Applicants also note that the March 3, 2003 final Official Action requested that the specification be amended to properly recite the claim of priority. Upon a favorable finding on appeal, Applicants intend to amend the specification to reflect the claiming of priority from U.S. Application No. 60/003157, filed Sept. 1, 1995; U.S. Application No. 08/576,238, filed on December 21, 1995; and PCT/CA96/00585, filed Aug. 30, 1996.

# 5. Summary of the Invention.

The Summary of the Invention is the same as that originally presented in the First Appeal Brief, and section 5 of the First Appeal Brief is incorporated herein by reference.

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## 6. Issues.

The issues in the present appeal are as follows:

- (1) Whether Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34 and 38 are properly rejected under 35 U.S.C. § 102 as being anticipated by Ruys (article entitled "Silicon-Doped Hydroxyapatite"), when Ruys does not teach each and every one of the claimed elements;
- (2) Whether Claims 10 and 26 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Ruys, when there is no basis or motivation to make the proposed modification;
- (3) Whether Claims 27, 29, 35 and 37 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Ruys in view of Davies (WO 94/26872), when there is no basis or motivation to make the proposed combination; and,
- (4) Whether Claim 33 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Ruys in view of Kijima (US 4,983,182), when there is no basis or motivation to make the proposed combination.

## 7. Grouping of Claims.

The *Grouping of Claims* is the same as that originally presented in the First Appeal Brief, and section 7 of the First Appeal Brief is incorporated herein by reference.

## 8. Argument.

- (1) Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34, and 38 are not properly rejected under 35 U.S.C. 102 because Ruys does not teach each and every element of the claimed invention.

  Argument (1) is the same as that originally presented in the First Appeal Brief, and section 8(1) of the First Appeal Brief is incorporated herein by reference.
- (2) Claims 10 and 26 are not properly rejected under 35 USC Section 103(a) because there is no basis in the art for modifying Ruys. *Argument* (2) is the same as that originally presented in the First Appeal Brief, and section 8(2) of the First Appeal Brief is incorporated herein by reference.

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(3) Claims 27, 29, 35 and 37 are not properly rejected under 35 USC Section 103(a) because there is no basis in the art for combining Ruys with Davies. *Argument* (3) is the same as that originally presented in the First Appeal Brief, and section 8(3) of the First Appeal Brief is incorporated herein by reference.

(4) Claim 33 is not properly rejected under 35 U.S.C. § 103(a) because each and every limitation of the claim is not taught by the combination of Ruys with Kijima.

Claim 33 stands rejected under 35 USC §103(a) as obvious in view of the combination of Ruys and Kijima. Claim 33 recites an implantable device coated with the composition of Claim 1. As shown in Argument (1) above, Ruys does not disclose each and every limitation of the composition of Claim 1. The Kijima reference does not further define the composition of Ruys. Rather, Kijima is cited for the proposition that it was known to coat an implant article with a tricalcium phosphate coating. Because the Kijima reference does not cure the failure of Ruys to disclose each and every limitation of the claimed composition, Claim 33 is not obvious in view of Ruys or Kijima, alone or in combination.

## **CONCLUSION**

Ruys cannot anticipate the claimed invention because Ruys is directed to a product that differs from the claimed invention. The Ruys product includes biodegradable tricalcium phosphate, stated to be undesired. In contrast, the claimed invention surprisingly provides bioactive stabilized insoluble tricalcium phosphate. Ruys does not assess what, if any, bioactivity the product produced therein has and certainly does not teach a product as claimed that is resorbable by osteoclasts and promotes secretion of mineralized bone matrix by osteoblasts. Accordingly Ruys does not teach every element of the claimed invention, and it cannot anticipate the claimed invention.

Ruys, alone or in combination with Davies, does not render the claimed invention obvious. There is simply no motivation to make the modifications suggested by the Examiner, and in fact, Ruys teaches away from using tricalcium phosphate. Ruys in combination with Kijima also does not render the claimed invention obvious because the combination does not

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teach each and every element of the claimed device. Thus, the Examiner has failed to make a prima facie case of obviousness.

In view of the arguments presented above, it is accordingly respectfully submitted that the Board reverse the rejections of record and order the immediate allowance of all pending claims in this case.

Respectfully submitted,

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